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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Standardized National Hypothesis Generating Questionnaire- New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It is estimated that each year roughly 1 in 6 Americans gets sick, 128,000 are hospitalized, and 3,000 die of foodborne

diseases. CDC and partners ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks, to limit the number of illnesses, and to learn how to prevent similar outbreaks from happening in the future.

Conducting interviews during the initial hypothesis-generating phase of multistate foodborne disease outbreaks presents numerous challenges. In the U.S. there is not a standard, national form or data collection system for illnesses caused by many enteric pathogens. Data elements for hypothesis generation must be developed and agreed upon for each investigation. This process can take several days to weeks and may cause interviews to occur long after a person becomes ill.

CDC requests OMB approval to collect standardized information, called the Standardized National Hypothesis-Generating Questionnaire, from individuals who have become ill during a multistate foodborne disease event. Since the questionnaire is designed to be administered by public health officials as part of multistate hypothesis-generating interview activities, this questionnaire is not expected to entail significant burden to respondents.

The Standardized National Hypothesis-Generating Core Elements Project was established with the goal to define a core set of data elements to be used for hypothesis generation during multistate foodborne investigations. These elements represent the minimum set of information that should be available for all outbreak-associated cases identified during hypothesis generation. The core elements would ensure that similar exposures would be ascertained across many jurisdictions, allowing for rapid pooling of data to improve the timeliness of hypothesis-generating analyses and shorten the time to pinpoint how and where contamination events occur.

The Standardized National Hypothesis Generating Questionnaire was designed as a data collection tool for the core elements, to be used when a multistate cluster of enteric disease infections is identified. The questionnaire is designed to be administered over the phone by public health officials to collect core elements data from case-patients or their proxies. Both the content of the questionnaire (the core elements) and the format were developed through a series of working groups comprised of local, state, and federal public health partners.

Burden hours are calculated by approximately 4,000 individuals identified during the hypothesis-generating phase of outbreak

investigations x 45 minutes/response. There are no costs to respondents other than their time. The total estimated annualized burden is 3,000 hours.

Estimated Annualized Burden Hours

| Type of respondents   | Form Name   | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs) |
|---|---|--------------------|---------------------------------|-----------------------------------|
| Ill individuals identified as part of an outbreak investigation | Standardized National Hypothesis Generating Questionnaire (Core Elements) | 4,000              | 1                               | 45/60                             |

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